UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ALLELE BIOTECHNOLOGY AND PHARMACEUTICALS, INC.,

Plaintiff,

-against-

REGENERON PHARMACEUTICALS, INC.,

Defendant.

OPINION & ORDER

20-CV-08255 (PMH)

PHILIP M. HALPERN, United States District Judge:

Allele Biotechnology and Pharmaceuticals, Inc. ("Allele" or "Plaintiff") commenced this action against Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Defendant") on October 5, 2020. (Doc. 1). Plaintiff presses one claim for relief in the Third Amended Complaint, the operative pleading, alleging that Defendant infringed United States Patent No. 10,221,221 ("the '221 Patent") which describes a monomeric yellow-green fluorescent protein that Plaintiff markets under the name mNeonGreen. (Doc. 114, "TAC").

Discovery concluded on January 26, 2024 pursuant to the Eleventh Amended Civil Case Discovery Plan and Scheduling Order. (Doc. 143). Before the Court are the parties' separate motions for summary judgment. Defendant seeks a judgement "that Allele is not entitled to any damages for pre-suit infringement for failure to comply with 35 U.S.C. § 287(a)" and "that Regeneron did not willfully infringe the '221 Patent." (Doc. 185). Plaintiff seeks a judgment "that the § 271(e)(1) Safe Harbor Defense does not immunize Regeneron's infringement of Allele's '221 Patent." (Doc. 179). The Court, during the April 10, 2024 pre-motion conference on the parties' separate motions for summary judgment, notified the parties that it would search the record and grant summary judgment, if appropriate, in accordance with Federal Rule of Civil Procedure 56(f). (Doc. 168).

Plaintiff filed, pursuant to the briefing schedule set forth by the Court, its memorandum of law in support of its motion for partial summary judgment. (Doc. 178, "Pl. Br."; Doc. 180, "Anstaett Decl."). Defendant filed its memorandum of law in support of its motion for partial summary judgment and in opposition to Plaintiff's motion. (Doc. 193, "Def. Br."; Doc. 196, "Ernst. Decl."). Plaintiff filed its reply in opposition to Defendant's motion and in support of its own motion (Doc. 182, "Pl. Reply"), and the motions were fully briefed with the filing of Defendant's reply (Doc. 193, "Def. Reply").

For the reasons set forth herein, Defendant's motion for summary judgment is DENIED and Plaintiff's motion for summary judgment is GRANTED.

BACKGROUND

The Court recites the facts herein only to the extent necessary to adjudicate the motion for summary judgment and draws them from the pleadings, the Rule 56.1 Statement and responses thereto (Doc. 190, "56.1 Stmt."), and the admissible exhibits proffered on this motion. Unless otherwise indicated, the facts cited herein are undisputed.

U.S. Patent No. 10,221,221 ("the '221 Patent") was filed on July 24, 2013 and issued on March 5, 2019. (56.1 Stmt. Def. ¶ 1). mNeonGreen is a fluorescent protein reagent used as a tool for applications in biotechnology and medicine including, among other things, to measure virus neutralizing activity. (56.1 Stmt. Pl. ¶ 1). mNeonGreen is not subject to FDA review or premarketing approval required by the Federal Food, Drug, and Cosmetic Act, or any other federal law. (56.1 Stmt. ¶ 4). Allele's '221 Patent claims mNeonGreen and is ineligible for a patent term extension under 35 U.S.C. § 156. (56.1 Stmt. Pl. ¶ 5). Allele licenses the use of mNeonGreen to academic and commercial entities. (Ernst Decl., Ex. 8 [Wang Dep. Tr.] at 64:6-68:15). Allele's

licensees distribute mNeonGreen plasmids to other entities who can use the plasmids to make the mNeonGreen protein. (*Id.* at 284:6-285:17; 56.1 Stmt. Def. ¶ 20).

Regeneron's REGEN-COV drug product, sold for administration to humans for the treatment of COVID-19, is a drug subject to FDA premarketing authorization and approval requirements. (56.1 Stmt. Pl. ¶ 2). mNeonGreen is not an ingredient in REGEN-COV, and REGEN-COV does not incorporate mNeonGreen in any way. (56.1 Stmt. Pl. ¶ 3). Regeneron used mNeonGreen to determine the effectiveness of various antibody candidates for potential inclusion in the antibody cocktail REGEN-COV. (56.1 Stmt. Pl. ¶ 6). Based in part on its use of mNeonGreen, Regeneron selected two antibodies that it determined as the optimal pair for inclusion in REGEN-COV. (56.1 Stmt. Pl. ¶ 7). Regeneron also used mNeonGreen to test the potency of manufactured lots of REGEN-COV and to test the REGEN-COV antibodies against COVID-19 variants. (56.1 Stmt. Pl. ¶ 8). Allele commenced the instant lawsuit on October 5, 2020, alleging infringement of the '221 Patent. (56.1 Stmt. Def. ¶ 2). Regeneron ceased its use of mNeonGreen in connection with REGEN-COV by November 19, 2020. (56.1 Stmt. Def. ¶ 35).

STANDARD OF REVIEW

Pursuant to Federal Rule of Civil Procedure 56, a court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed R. Civ. P. 56(a). "A fact is 'material' if it 'might affect the outcome of the suit under the governing law,' and is genuinely in dispute 'if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.'" *Liverpool v. Davis*, No. 17-CV-03875, 2020 WL 917294, at *4 (S.D.N.Y. Feb. 26, 2020) (citing *Anderson v. Liberty*

Lobby, Inc., 477 U.S. 242, 248 (1986)).[1] "'Factual disputes that are irrelevant or unnecessary' are not material and thus cannot preclude summary judgment." *Sood v. Rampersaud*, No. 12-CV-05486, 2013 WL 1681261, at *1 (S.D.N.Y. Apr. 17, 2013) (quoting *Anderson*, 477 U.S. at 248). "The question at summary judgment is whether a genuine dispute as to a *material* fact exists—not whether the parties have a dispute as to any fact." *Hernandez v. Comm'r of Baseball*, No. 22-343, 2023 WL 5217876, at *5 (2d Cir. Aug. 15, 2023); *McKinney v. Cty. of Middletown*, 49 F.4th 730, 737 (2d Cir. 2022)) ("the party opposing summary judgment must present competent evidence that creates a genuine issue of material fact).

The Court's duty in adjudicating motions for summary judgment is "not to resolve disputed issues of fact but to assess whether there are any factual issues to be tried." *McKinney*, 49 F.4th at 738 (quoting *Wilson v. Nw. Mut. Ins. Co.*, 625 F.3d 54, 60 (2d Cir. 2010)). Indeed, the Court's function is not to determine the truth or weigh the evidence. *Porter v. Dartmouth-Hitchcock Med. Ctr.*, No. 92 F.4th 129, 147 (2d Cir. 2024) ("[T]he court may not make credibility determinations or weigh the evidence." (quoting *Kaytor v. Electric Boat Corp.*, 609 F.3d 537, 545 (2d Cir. 2010))). The task is material issue spotting, not material issue determining. Therefore, "where there is an absence of sufficient proof as to one essential element of a claim, any factual disputes with respect to other elements of the claim are immaterial." *Bellotto v. Cnty. of Orange*, 248 F. App'x 232, 234 (2d Cir. 2007) (quoting *Salahuddin v. Goord*, 467 F.3d 263, 281 (2d Cir. 2006)).

"It is the movant's burden to show that no genuine factual dispute exists." *Vermont Teddy Bear Co. v. 1-800 Beargram Co.*, 373 F.3d 241, 244 (2d Cir. 2004) (citing *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970)). When evaluating motions for summary judgment, "the Court

[1] Unless otherwise indicated, case quotations omit all internal citations, quotation marks, footnotes, and alterations.

reviews each party's motion on its own merits and draws all reasonable inferences in favor of the non-moving party." *N. Star IP Holdings, LLC v. Icon Trade Servs., LLC*, 710 F. Supp. 3d 183, 197 (S.D.N.Y. 2024) (citing *Schwebel v. Crandall*, 967 F.3d 96, 102 (2d Cir. 2020); *Coutard v. Mun. Credit Union*, 848 F.3d 102, 114 (2d Cir. 2017)). "In determining whether there are genuine issues of material fact, a court is required to resolve all ambiguities and draw all permissible factual inferences in favor of the party against whom summary judgment is sought." Id. Once the movant has met its burden, the non-movant "must come forward with specific facts showing that there is a genuine issue for trial." *Liverpool*, 2020 WL 917294, at * 4 (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986)). The non-movant cannot defeat a summary judgment motion by relying on "mere speculation or conjecture as to the true nature of the facts." *Id.* (quoting *Knight v. U.S. Fire Ins. Co.*, 804 F.2d 9, 12 (2d Cir. 1986)). However, if "there is any evidence from which a reasonable inference could be drawn in favor of the opposing party on the issue on which summary judgment is sought, summary judgment is improper." *Sood*, 2013 WL 1681261, at *2 (citing *Sec. Ins. Co. of Hartford v. Old Dominion Freight Line Inc.*, 391 F.3d 77, 83 (2d Cir. 2004)).

Should there be no genuine issue of material fact, the movant must also establish its entitlement to judgment as a matter of law. *See Glover v. Austin*, 289 F. App'x 430, 431 (2d Cir. 2008) ("Summary judgment is appropriate if, but only if, there are no genuine issues of material fact supporting an essential element of the plaintiffs' claim for relief."); *Pimentel v. City of New York*, 74 F. App'x 146, 148 (2d Cir. 2003) (holding that because plaintiff "failed to raise an issue of material fact with respect to an essential element of her claim, the District Court properly granted summary judgment dismissing that claim"). Simply put, the movant must separately establish that the law favors the judgment sought.

ANALYSIS

The issues associated with Defendant's motion for summary judgment will be dealt with first and seriatim.

I. Marking Statute Defense

Regeneron seeks, in the first branch of its motion for partial summary judgment, a judgement "that Allele is not entitled to any damages for pre-suit infringement for failure to comply with 35 U.S.C. § 287(a)." (Doc. 185). Regeneron argues that "[b]ecause Allele and its licensees failed to mark or provide actual notice before suit, summary judgment of no damages for pre-suit infringement is proper." (Def. Br. at 6). Specifically, Regeneron argues that (i) Allele did not plead compliance with 35 U.S.C. § 287 ("Marking Statute"); (ii) Allele and its licensees failed to mark mNeonGreen plasmids, foreclosing constructive notice as a matter of law; and (iii) Allele did not provide actual pre-suit notice to Regeneron. (*Id.* at 5-13). Allele responds by arguing that (i) it had no obligation to mark is unpatented plasmids; (ii) there is a factual dispute as to whether plasmids were distributed during the relevant time period; and (iii) Regeneron has not met the burden of production for a marking defense. (Pl. Reply at 9-13).

Allele argues, and Regeneron concedes, that it does not sell mNeonGreen, which is a fluorescent protein and the patented article at issue in this litigation. (*See* Pl. Reply at 10; Def. Reply at 3.) Allele instead provides its licensees with a mNeonGreen plasmid. (*Id.*). It is undisputed that "[n]either Allele nor its licensees (Addgene and Montana Molecular) marked the mNeonGreen palsmids with the '221 Patent or with a website link, prior to the Complaint." (56.1 Stmt. Def. ¶ 4). The federal circuit has explained that a plasmid is a "circular piece of DNA . . . that is inserted into a host cell to produce (or 'express') a protein." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1321 (Fed. Cir. 2003). The plasmid "carries the gene encoding for the protein of

interest (in this case [mNeonGreen]), a marker that assures that the [plasmid] is properly introduced into the host cell, and a promoter site that the host will recognize to transcribe the [plasmid's] DNA." *Id.* The Court must determine, as a threshold issue, whether the Marking Statute applies to the plasmids that Allele provides to licensees of mNeonGreen.

"Pursuant to 35 U.S.C. § 287(a), a patentee who makes or sells a patented article must mark his articles or notify infringers of his patent in order to recover damages." *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1365 (Fed. Cir. 2017) ("*Arctic Cat I*"). "If a patentee who makes, sells, offers for sale, or imports his patented articles has not 'given notice of his right' by marking his articles pursuant to the marking statute, he is not entitled to damages before the date of actual notice." *Id.* at 1366 (quoting *Dunlap v. Schofield*, 152 U.S. 244, 248 (1894)). The Federal Circuit has held that "an alleged infringer who challenges the patentee's compliance with § 287 bears an initial burden of production to articulate the products it believes are unmarked 'patented articles' subject to § 287 *Arctic Cat I*, 876 F.3d at 1368. This initial burden of production "is a low bar" and the alleged infringer "need only put the patentee on notice that he or his authorized licensees sold specific unmarked products which the alleged infringer believes practice the patent." *Id.* Regeneron's initial burden on summary judgment is therefore "a burden of production, not one of persuasion or proof." *Id.* "Once the alleged infringer meets its burden of production, however, the patentee bears the burden to prove the products identified do not practice the patented invention." *Id.*

Allele argues that the Marking Statute does not apply to the mNeonGreen plasmids because "the plasmids in question are not a *component* of [mNeonGreen], but a blueprint that instructs cells how to make the patented protein." (Pl. Reply at 11.) Regeneron argues, relying on *Amsted Indus. Inc. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 180 (Fed. Cir. 1994), that Allele was required to

mark the mNeonGreen plasmids. (Def. Reply at 11). *Amsted* involved a patent for a "railroad car underframe structure" which consisted of a "center plate in combination with several other components." *Id.* at 180. The patentee sold the center plate component separately "with the expectation that [customers] would use that element to make and sell the patented invention" and that the patentee "provided its customers with installation drawings which instruct how to assemble the center plate, along with other components, according to the teachings of the patent." *Id.* at 185. The Federal Circuit held that the center plate was subject to the Marking Statute and that the patentee could have either marked the center plate themselves or alternatively, "could have sold its plates with a requirement that its purchaser-licensees mark the patented products." *Id. Amsted* is distinguishable. The plasmid that Allele provides to licensees of mNeonGreen is unlike the center plate in *Amsted* in that the plasmid is not a component of the mNeonGreen protein but rather it is "a small DNA molecule" that can "be used by a person or entity to make the mNeonGreen protein in a lab." (Doc. 182-10 at ¶ 103). Indeed, it is undisputed that "mNeonGreen is not an ingredient in REGEN-COV, and REGEN-COV does not incorporate mNeonGreen in any way." (56.1 Stmt. Pl. ¶ 3). Requiring Allele to mark the mNeonGreen plasmid does not fulfill the Marking Statute's "policy goal of notifying the public concerning the patent status of its items in commerce" because the mNeonGreen protein would not be marked as a result of the plasmid being marked. *Amsted*, 24 F.3d at 185.

Allele and its licensees did not have an obligation under the Marking Statute to mark the mNeonGreen plasmids with the '221 Patent number. Accordingly, the branch of Regeneron's motion for summary judgment seeking to preclude damages for pre-suit infringement under the Marking Statute is DENIED.

II. Willful Infringement

Regeneron seeks, in the second and final branch of its motion for partial summary judgment, a judgement "that Regeneron did not willfully infringe the '221 Patent." (Doc. 185). Regeneron argues that "[b]ecause Allele cannot establish that Regeneron had any pre-suit knowledge of the '221 Patent—a necessary element of willfulness—summary judgment of no willful infringement is warranted." (Def. Br. at 16). Allele argues that "the evidence here unquestionably would support a jury finding that Regeneron's unsanctioned use of [mNeonGreen] presented an unreasonable risk of patent infringement." (Pl. Br. at 5).

Willful infringement "is a question of fact" and to establish willfulness, "the patentee must show the accused infringer had a specific intent to infringe at the time of the challenged conduct." *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 987 (Fed. Cir. 2021). "[K]nowledge of the asserted patent and evidence of infringement, although necessary, is not sufficient for a finding of willfulness," rather, "willfulness requires deliberate or intentional infringement." *Fleet Engineers, Inc. v. Mudguard Techs., LLC*, No. 2022-2001, 2023 WL 5219773, at *8 (Fed. Cir. Aug. 15, 2023) (citing *Bayer*, 989 F.3d at 987); *see also FloodBreak, LLC v. Art Metal Indus., LLC*, No. 18-CV-00503, 2020 WL 5300250, at *15 (D. Conn. Sept. 3, 2020) ("the question of willful infringement turns on whether, at the time of the defendant's infringement, the defendant knew or, it was so obvious that the defendant should have known, that its actions constituted infringement of a valid and enforceable patent").[2] "Summary judgment is appropriate on a willful infringement claim if

[2] Allele argues that "*Halo* made it clear that reckless behavior may be sufficient to support a finding of willful infringement." (Pl. Reply at 7 (citing *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 106 (2016)). Allele misstates the Supreme Court's holding in *Halo*, where the Supreme Court noted that "it is not clear why an independent showing of objective recklessness—by clear and convincing evidence no less—should be a prerequisite to enhanced damages" and held that "subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless." 589 U.S. at 104. The Federal Circuit noted that *Halo* "rejected the objective recklessness requirement" in *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 14 F.4th 1323, 1328 n.1 (Fed. Cir. 2021).

Defendants can point to an absence of record evidence concerning its knowledge of the patent-in-suit and its claims." *Kewazinga Corp. v. Microsoft Corp.*, 558 F. Supp. 3d 90, 119 (S.D.N.Y. 2021) (citing *Olaf Sööt Design, LLC v. Daktronics, Inc.*, 325 F. Supp. 3d 456, 461 (S.D.N.Y. 2018)).

Allele argues that there is "ample circumstantial evidence" that Regeneron had pre-suit knowledge of the '221 Patent. While the record does not contain any direct evidence that Regeneron had pre-suit knowledge of the '221 Patent, "evidence of pre-suit knowledge of a patent can be circumstantial." *Kewazinga*, 558 F. Supp. 3d at 119 (citing *SIMO Holdings Inc. v. Hong Kong uCloudlink Network Tech. Ltd.*, 396 F. Supp. 3d 323, 334 (S.D.N.Y. 2019)). Ben Fulton, a senior scientist at Regeneron responsible for its first use of mNeonGreen, testified at his deposition that he reviewed a published paper regarding mNeonGreen entitled *A Bright Monomeric Green Fluorescent Protein Derived From Branchiostoma Lanceolatum*. (Ernst Decl., Ex. 36 [Fulton Dep. Tr.] at 17:6-21:5). Fulton testified that he subsequently cited this paper in his own publications. (*Id.*). The first page of that paper discloses that "Allele has filed for patent protection of mNeonGreen." (*Id.*, Ex. 40). Fulton was asked at his deposition whether he did anything to investigate whether or not there was a patent covering mNeonGreen and he responded that "there was nothing obvious to draw us to the conclusion that there was a patent on mNeon[Green] and we were not aware of it." (Fulton Dep. Tr. at 100:4-13). Fulton further testified that he was a "basic science researcher" and did not have knowledge regarding Regeneron's licensing of any fluorescent proteins. (*Id.* at 153:14-25).

Dr. Ralph Jimenez, who is retained as an expert by Regeneron, states in his report that Regeneron has previously licensed the use of two similar fluorescent proteins. (Ernst. Decl., Ex. 16 [Jimenez Rep.] ¶¶ 148, 152). Abbas Hussain, a senior director of corporate development at Allele responsible for licensing its technology, testified at his deposition that he called

Regeneron's corporate headquarters multiple times in June and July of 2020 to initiate licensing discussions for Regeneron's use of mNeonGreen. (Ernst. Decl., Ex. 7 [Hussain Dep. Tr] at 125:24-132:15). Hussain testified that he could not recall whether he specifically referenced the '221 Patent during these calls. (*Id.* at 128: 13-20). He further testified that despite calling multiple times he "could not get past reception" and that "it got to the point where I was calling and, honestly, they were just picking up and hanging up the phone." (*Id.* at 130:9-22). Hussain sent an email to "business.development@regeneron.com" on July 2, 2020 with the subject line "Technology Licensing (mNeonGreen)" in which Hussain provided a link to a paper written by Fulton and other Regeneron employees which cited to a paper about mNeonGreen, and Hussain further stated that "[t]he fluorescent protein mNeonGreen that is used in this paper is subject to licensing from Allele Biotechnology. I would like to speak with someone regarding this, so if someone could please reach out to me promptly I would appreciate it." (Ernst. Decl., Ex. 34). Hussain sent an email to "business.development@regeneron.com" on July 9, 2020 with the subject line "Second Notice Regarding Unlicensed Use of Technology" in which Hussain stated, "I am emailing regarding the unlicensed use of mNeonGreen. I sent an email on 7/2 and have also reached out via the contact form on your webpage and have not heard from anyone. Please contact me so we can discuss this matter, thank you." (*Id.*, Ex. 35). Regeneron's Rule 30(b)(6) corporate representative, Srilakshmi Ravi, testified at her deposition that the "business.development@regeneron.com" that Hussain emailed twice was set up and maintained by Regeneron, and that the email address was posted on Regeneron's website. (Ernst Decl., Ex. 38 [Ravi Dep. Tr.] at 17:16-27:14). Ravi further testified that Regeneron's head of business development, Nouhad Husseini, was tasked with monitoring

that email address. (*Id.*).[3] Jiwu Wang, Allele's President and Chief Operating Officer, corroborated Hussain's testimony at his deposition where he testified that he directed Hussain to initiate licensing discussions with Regeneron and that Hussain attempted to do so by sending Regeneron "multiple emails" and making "multiple phone calls." (*Id.*, Ex. 8 [Wang Dep. Tr.] at 324:17-335:5).

Allele need not, in opposing Regeneron's motion for summary judgment, prove willful infringement. Rather, as Judge Woods held in *Kewazinga*, summary judgment on willful infringement is appropriate where a defendant "can point to an absence of record evidence concerning its knowledge of the patent-in-suit and its claims." 558 F.Supp.3d at 119. In other words, Regeneron must establish that there is a failure of proof with respect to whether it had pre-suit knowledge of the '221 Patent. Regeneron has failed to meet its burden on summary judgment. There is evidence, in the form of deposition testimony from Fulton, that Regeneron knew that Allele had applied for a patent on mNeonGreen. (Fulton Dep. Tr. at 17:6-21:5). There is also evidence, in the form of deposition testimony from Wang and Hussain, that Regeneron received multiple calls and emails from Allele's representatives to initiate licensing discussions. (Wang Dep. Tr. at 324:17-335:5; Hussain Dep. Tr. at 125:24-132:15). Hussain's emails to Regeneron, in which Hussain specifically states that he was attempting to contact Regeneron to discuss "the unlicensed use of mNeonGreen," are also circumstantial evidence of willfulness. (Ernst Decl., Exs. 34, 35). Further, Regeneron's expert submitted a report stating that Regeneron previously entered

[3] Ravi testified that she spoke to Husseini regarding the "business.development@regeneron.com" email account in preparation for her deposition and Husseini told her that "as time went on, [Husseini], you know, monitored less and less, because there was no relevant information there. [Husseini] monitored very infrequently in 2019 and not at all in 2020." (Ravi Dep. Tr. at 19:5-20:6). Ravi further testified that Husseini had an assistant that worked for him but that Husseini "was the only one in his department who had access to this e-mail box." (*Id.* at 38:22-39:7). Ravi testified that she did not ask Husseini why Regeneron maintained an email account that was not being monitored or why the purportedly unmonitored email address continued to be posted on Regeneron's website. (*Id.* at 20:7-20; 25:20-26:5).

into license agreements for the use of fluorescent proteins similar to mNeonGreen. (Jimenez Rep. ¶¶148, 152).

A rational jury could infer from these facts, when drawing all reasonable inferences in favor of Allele, that Regeneron had pre-suit knowledge of the '221 Patent.[4] Accordingly, the branch of Regeneron's motion for summary judgment on the issue of willful infringement of the '221 Patent is DENIED.[5]

The Court now turns to Plaintiff's motion for summary judgment.

III. Safe Harbor Defense

Allele seeks, in its motion for summary judgment, a judgment "that the § 271(e)(1) Safe Harbor Defense does not immunize Regeneron's infringement of Allele's '221 Patent." (Doc. 179). Allele argues, relying on *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008), that mNeonGreen is a research tool not subject to FDA approval and therefore not subject to Section 271(e)(1)'s safe harbor defense. (Pl. Br. at 8-13). Regeneron argues that "the safe harbor should apply to Regeneron's use of the patented mNeonGreen markers as a component in one of many tests to generate data for the FDA." (Def. Br. at 24).

[4] The Court's holding with respect to Regeneron's pre-suit willful infringement applies to post-suit willful infringement as well. Regeneron argues that "[t]he record reflects no post-suit willful infringement by Regeneron." Not so. Fulton testified at his deposition that "[t]he last use of mNeonGreen [by Regeneron] that I am aware of was for the oncolytic virus program in January of 2021." (Fulton Dep. Tr. at 29:7-14). Regeneron has failed to show an absence of record evidence with respect to post-suit willful infringement. The Court holds that a rational jury could find post-suit willful infringement by Regeneron and denies the branch of Regeneron's motion for summary judgment on post-suit willfulness.

[5] Regeneron further argues that "Allele also cannot establish that Regeneron engaged in 'deliberate or intentional infringement' prior to suit." (Def. Br. at 16). The question of whether Regeneron's conduct was "deliberate or intentional" is a question for the jury. The Federal Circuit held *in Eko Brands, LLC v. Adrian Rivera Maynez Enterprises, Inc.*, that "the concept of 'willfulness' requires a jury to find no more than deliberate or intentional infringement." 946 F.3d 1367, 1378 (Fed. Cir. 2020). "The question of enhanced damages is addressed by the court once an affirmative finding of willfulness has been made." *Id.* Here, a jury could make a finding of deliberate or intentional infringement from the record evidence. To the extent Regeneron seeks summary judgment on the issue of deliberate or intentional infringement, it is denied.

Section 271(e)(1) provides that it is not infringement for a party to use a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1). The Federal Circuit has held that "[d]espite the broad contours of the exemption, some activities are outside its protection," for example, "research tools or devices that are not themselves subject to FDA approval may not be covered." *Momenta Pharms., Inc. v. Teva Pharms. USA Inc.*, 809 F.3d 610, 619 (Fed. Cir. 2015) (citing *Proveris*, 536 F.3d at 1265-66). The Federal Circuit defined "research tools" in this context to mean "tools that scientists use in the laboratory including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines." *Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1347 n.3 (Fed. Cir. 2007) (citing 64 Fed.Reg. 72,090, 72092 n. 1 (Dec. 23, 1999)).

Proveris involved cross motions for summary judgment on the issue of whether defendant's use of plaintiff's patented tool was immunized by the safe harbor provision of Section 271(e)(1). 536 F.3d at 1260. The district court granted summary judgment in the plaintiff's favor, dismissing the defendant's safe harbor affirmative defense, and the Federal Circuit affirmed. *Id.* The patented tool at issue in *Proveris* was an optical spray analyzer that "allows researchers to study and optimize the delivery of various aerosol-based drugs." 536 F.3d at 1258. The Federal Circuit held that the Section 271(e)(1) safe harbor provision did not apply for two reasons. First, the defendant was "not within the category of entities for whom the safe harbor provision was designed to provide relief" because the provision is intended to protect "a party seeking FDA approval for a product *in order to enter the market to compete with patentees*." *Id.* at 1265 (emphasis added). Second, the patented optical spray analyzer in that case was not a "patented

invention" as that term is used in Section 271(e)(1) because it was "not subject to the premarket approval required by the FDCA." *Id.*[6]

Regeneron relies on the Federal Circuit's decision in *Classen Immunotherapies, Inc. v. Elan Pharms., Inc.*, 786 F.3d 892, 897 (Fed. Cir. 2015) to argue that the safe harbor provision has been applied to patents not subject to FDA approval or not eligible for a patent term extension. (Def. Br. at 20). *Classen* is distinguishable because it contains no analysis of whether the patent at issue constituted a research tool, and no analysis of whether the patent at issue was a "patented invention" for the purposes of section 271(e)(1). 786 F.3d 892. Rather, the issue before the Federal Circuit in *Classen* was whether "the district court erred in finding [the allegedly infringing] activities exempt under the safe harbor because, according to [plaintiff], those activities are merely routine post-approval reporting to the FDA." *Classen*, 786 F.3d at 896–97. *Classen* is therefore inapplicable to the Court's analysis of Allele's motion for summary judgment.

Regeneron also relies on *Teva Pharms. USA, Inc. v. Sandoz Inc.*, No. 09-CV-10112, 2013 WL 3732867, at *3 (S.D.N.Y. July 16, 2013) to argue that "the Safe Harbor should apply to Regeneron's use of the patented mNeonGreen markers as a component in one of many tests to generate data for the FDA." (Def. Br. at 24). *Teva* involved a plaintiff that had a patent on a branded multiple sclerosis drug—Copaxone—that brought suit against defendants who allegedly infringed on the Copaxone patent in their efforts "to obtain approval for generic forms of Copaxone that

[6] The Federal Circuit noted in *Proveris* that its interpretation of "patented invention" in the safe harbor provision "achieves the same kind of fit, or symmetry" between Section 271(e)(1) and Section 156(f) that the Supreme Court sought to achieve between those two provisions in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990). The Federal Circuit went on to explain this symmetry by explaining that "[b]ecause Proveris's patented product is not subject to a required FDCA approval proves, it is not eligible for the benefit of the patent term extension afforded by 35 U.S.C. § 156(f). At the same time, because Innova's OSA device also is not subject to a required FDCA approval process, it does not need the safe harbor protection afforded by 35 U.S.C. § 271(e)(1)." *Id.* at 1265-66.

would be competing [products]." *Id.* at *1. Judge Forrest granted defendants' motion to dismiss in that case, holding that defendants' use of the patented product "in connection with preparation of an ANDA" approval for the competing generic products was protected under the safe harbor provision of Section 271(e)(1). *Id.* at *9. The holding reached by Judge Forrest is entirely consistent with *Proveris* because the defendants in *Teva* are precisely "within the category of entities for whom the safe harbor provision was designed to provide relief." *Proveris*, 536 F.3d at 1265. The defendants in *Teva*, unlike Regeneron and the defendants in *Proveris*, were "seeking FDA approval for a product in order to enter the market to compete with patentees." *Id. Proveris* clearly contemplates that such defendants are entitled to protection under the safe harbor provision. The instant case is distinguishable from *Teva* because here, it is undisputed that Regeneron was not seeking FDA approval "in order to enter the market to compete with Allele and its mNeonGreen technology." (56.1 Stmt. ¶¶ 9-10).Both of the reasons provided by the Federal Circuit for its holding in *Proveris* apply to the instant case with equal force.[7] First, it is undisputed that "Regeneron's use of mNeonGreen was not for the purpose of entering the market with a product that competes with mNeonGreen" and Regeneron was not seeking FDA approval "in order to enter the market to compete with Allele and its mNeonGreen technology." (56.1 Stmt. ¶¶ 9-10). Second, it is undisputed that "mNeonGreen is not subject to FDA review or pre-marketing approval." (56.1 Stmt. ¶ 4). mNeonGreen, like the patented optical spray analyzer at issue in

[7] Another district court reached this same conclusion, albeit on a motion to dismiss. The issue of whether an infringer's use of mNeonGreen is subject to the safe harbor provision was discussed in *Allele Biotechnology & Pharms., Inc. v. Pfizer, Inc.*, No. 20-CV-01958, 2021 WL 1749903 (S.D. Cal. May 4, 2021). Allele argued in that case that the safe harbor provision did not apply "as a matter of law because the safe harbor provision does not apply to 'research tools' that are used in the development of FDA regulatory submissions, but are not themselves subject to FDA premarket approval." *Id.* at *4. Judge Huff denied the motion to dismiss in that case noting that "under *Proveris*, research tools that are not themselves subject to FDA approval are excluded from the Section 271(e)(1) safe harbor" and holding that "Defendants have failed to demonstrate that [mNeonGreen] is a 'patented invention' for the purposes of Section 271(e)(1)." *Id.* at *5.

Proveris, was used to measure the effectiveness of pharmaceutical products in development. Specifically, it is undisputed that Regeneron "used mNeonGreen in neutralization assays to determine the effectiveness of antibody candidates for potential inclusion in the antibody cocktail REGEN-COV." (56.1 Stmt. ¶ 6). mNeonGreen, as a patented product not subject to a required FDCA approval process, is not a "patented invention" for purposes of the safe harbor provision of Section 271(e)(1). mNeonGreen, like the optical spray analyzer in *Proveris*, is therefore appropriately characterized as a research tool that is not under the scope of the safe harbor provision of Section 271(e)(1).

Accordingly, the Allele's motion for summary judgment on the issue of the safe harbor provision of Section 271(e)(1) is GRANTED. The Court holds that the safe harbor provision of Section 271(e)(1) does not immunize Regeneron's infringement of the '221 Patent.

CONCLUSION

For the foregoing reasons, Defendant's motion for summary judgment is DENIED and Plaintiff's motion for summary judgment is GRANTED.

The Clerk of Court is respectfully directed to terminate the motions pending at Doc. 177, Doc. 185, and Doc. 192. The parties are directed to file, by November 4, 2024, the pretrial materials set forth in Rules 6(A) and 6(B) of the Court's Individual Practices in Civil Cases.

SO ORDERED.

Dated: White Plains, New York
October 4, 2024

PHILIP M. HALPERN
United States District Judge